REMARKS

Claims 14-18 were objected to for ailing to set forth any further structural limitation. It is seen that Claims 14-16 and 18 provide further details of a structural element, the user control of Claim 10. As can be seen by Claim 10, the user control is characterized by the manner in which it affects the relative opacities of the combined display of an anatomical structural image and a parametric perfusion image. Claims 14-16 and 18 provide further limitations of how the user control acts to set the relative image opacities. Claim 17 adds an additional structural element, a display. Accordingly it is respectfully submitted that Claims 14-18 clearly and appropriately delineate the present invention.

Claims 10-19 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, Claim 10 was objected to a describing "a source" which is not defined in the specification. The "source" language in line 4 has been canceled and replaced by an image processor which produces anatomical structural images, which is supported by the B mode image processor 36 on page 5 and the Doppler image processor 40 on page 6. The "source" language in line 6 has been replaced by a parametric perfusion image processor which is supported by specification description from page 9, line 18 to page 10, line 18. Accordingly it is respectfully submitted that Claims 10-19 comply with the written description requirement.

Claims 1-3 and 5-9 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claim 1 has been amended to provide structure with which the claimed method is carried out, an ultrasonic image display. Furthermore, these method claims are seen to describe the transformation of an anatomical structural image and a parametric perfusion image into a registered display of variable relative opacities. The Federal Circuit Court has specifically recognized the patentability of diagnostic image processing in *In re Bilski*, 545 F.3d. 943 (Fed. Cir. 2008) where the court favorably analyzed the earlier decision of *In re Abele*, 684 F.2d 902 (CCPA 1982), saying:

> "[W]e held one of Abele's dependent claims to be drawn to patent-eligible subject matter where it specified that "said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner." *Abele*, 684 F.2d at 908-09. This data clearly represented physical and tangible objects, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible.

> "We further note for clarity that the electronic transformation of the data itself into a visual depiction in *Abele* was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented."

Bilski, 545 F.3d at 963. It is respectfully submitted that Claims 1-3 and 5-9 describe the transformation of image data from tissue and blood flow into a particular visual depiction of relative opacities as approved for patentability by the Court in *Bilski*.

Claims 1, 10 and 14-19 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,720,291 (Schwartz) which was cited by applicants. These claims have been amended to more clearly define the present invention. The amendments of Claims 1 and 10 are supported by the specification paragraphs beginning on page 2, line 26 (harmonic contrast agents), page 9, line 18 and page 10, line 8 (parametric perfusion image processing), and original Claim 7 (opacity range).

Amended Claim 1 describes a method of simultaneously displaying a two or three dimensional parametric perfusion image and an anatomical structural image of the region of interest corresponding to the parametric perfusion image on an ultrasonic image display, comprising acquiring an anatomical structural image of a region of interest of a subject comprising tissue containing blood flow; acquiring harmonic signal components from a harmonic contrast agent in the region of interest of the subject; processing harmonic signal components of corresponding locations in a sequence of images to form a parametric image of a perfusion characteristic of the tissue of the region of interest; and displaying the parametric perfusion image in anatomical registration with the anatomical structural image, wherein the relative opacity of the registered parametric image and anatomical structural image is variable over a range of relative opacities. The present invention solves two problems, one of which is correlating for the clinician a parametric image to the tissue and blood flow to which the parameters of the image relate. The other problem solved is doing this in an anatomically visual manner, as the two images are of the same anatomy and simply overlaying the two images would cover the underlying image. These problems manifest themselves with both 2D and 3D anatomical comparisons. As shown in Figs. 15A-15E of the present application, by enabling the clinician to vary the opacity of one or both of the anatomically registered images, the clinician can fade back and forth between an image of the tissue and blood flow and an image of the parameter in registration therewith, or a combination of the two. The clinician can thus see a defect such as a perfusion anomaly in the perfusion image and immediately fade to the corresponding tissue to quickly identify and confirm an infarcted region of the myocardium, for instance.

Amended Claim 1 contains numerous elements not found in Schwartz. The method of Claim 1 is recited to be for two or three dimensional imaging. Schwartz is only applicable to 3D imaging. Amended Claim 1 recites the use of a parametric perfusion image. Schwartz does not relate to perfusion imaging but to arterial blood flow where the parameter is flow velocity within the vessel. Schwartz is unrelated to tissue perfusion. Amended Claim 1 recites the use of harmonic signal components from a harmonic contrast agent. Schwartz does not mention any use of contrast agents. For these reasons it is respectfully submitted that Claim 1 cannot be anticipated by Schwartz.

Amended Claim 10 describes a diagnostic imaging system for displaying a two or three dimensional parametric perfusion image in anatomical registration with a two or three dimensional anatomical structural image of a region of interest of a subject comprising an image processor which produces anatomical structural images of a region of interest of a subject comprising tissue containing blood flow; a contrast signal processor which produces harmonic signals received from a harmonic contrast agent in the region of interest; a parametric perfusion image processor responsive to harmonic signals from corresponding locations in a sequence of images which produces a parametric perfusion image of the tissue of the region of interest of the subject; a display coupled to the source of anatomical structural images and the parametric perfusion image processor which displays an anatomical structural image and a corresponding parametric perfusion image of the same region in anatomical registration; a display processor coupled to the display which acts to set the relative opacity of the registered anatomical structural image and parametric perfusion image; and a user control, coupled to the display processor, by which a user can set the relative opacity of the registered anatomical structural image and parametric perfusion image. Amended Claim 10 describes a system for displaying two or three dimensional images. Schwartz is only applicable to 3D imaging. Amended Claim 10 recites the use of a parametric perfusion image. Schwartz does not relate to perfusion imaging but to arterial blood flow where the parameter is flow velocity within the vessel. Schwartz is unrelated to tissue perfusion. Amended Claim 10 recites the use of harmonic signals from a harmonic contrast agent. Schwartz does not mention any use of contrast agents. For these reasons it is respectfully submitted that Claim 10 and its dependent Claims 14-19 cannot be anticipated by Schwartz.

Claims 3-4 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schwartz in view of US Pat. pub. no. 2004/0254440 (Pedrizzetti et al.) Schwartz is dealing with a problem with volumetric (3D) imaging which is that, when an image of a

volume of tissue is acquired, blood vessels inside the tissue cannot be seen because they are obscured by the tissue in front of the, the tissue between the viewer (the probe) and the blood vessels. Schwartz's solution to the problem is to enable the tissue to be rendered as semitransparent so that the viewer can "see through" the tissue and observe the inner blood vessels. Schwartz does this by using opacity control parameters in his rendering algorithm as explained in the paragraph spanning cols. 5-6 which he uses to render tissue and blood flow images together. This means that, each time Schwartz wants to show a different transparency for the tissue, he has to re-render the 3D image.

Pedrizzetti et al. are forming parametric perfusion images in the standard manner of calculating perfusion parameters for points in a planar 2D image, referred to by Pedrizzetti et al. as a "transmural cut TC_i". See paragraph [0084] of Pedrizzetti et al. As explained in the paragraph beginning on page 9, line 18 of the present specification, perfusion parameters are calculated from changing pixels values at the same location representing the presence of contrast over a time sequence of images. Since the heart is continuously beating and the myocardium is moving, Pedrizzetti et al. are concerned with aligning successive images so that common image locations are aligned over the sequence. Pedrizzetti et al. then form their images in the manner conventionally used for 2D parametric images, which is to show the parametric data overlaying the tissue structure. This is the time-honored way of displaying the earliest 2D parametric images, colorflow images. As explained in the paragraph beginning on page 2, line 7, colorflow images are formed by overlaying a color image of blood flow velocities over a B mode tissue image. While the color image of the blood flow could be shown alone, such an image lacks tissue landmarks that enable a clinician to orient the image location in the body in relation to vessel walls, valves and other nearby tissue. The B mode image frames the flow image with tissue landmarks that provides this diagnostic information. In B mode images the signals from blood cells in arteries and veins are very small and thus the lumens of vessels appear black in B mode images; the lumens provide no information to the clinician. The colorflow image overlays the flow velocity colors in these otherwise empty voids. Thus, no image information from the B mode tissue image is obscured but instead, the filled-in vessels provide information on the flow velocities in these vessels. There is no need to alter the opacity of either image, because nothing in the blood vessels is obscured by the flow color, or vice versa. Pedrizzetti et al. takes the same approach, showing perfusion parameters oriented by the surrounding tissue in the 2D image plane.

The present inventors have discerned, however, that a perfusion image does not depict blood flow in a large vessel, but the supply of blood to the tiny capillaries which supply the blood from larger vessels to the tissue itself. They have recognized that the small structure of individual capillaries cannot be resolved in the typical ultrasound images of tissue. They have further discerned that the subtle variation of perfusion in these tiny vessels is affected by the density of the tissue in which the microvasculature is located. The shading of the tissue structure can thus affect the visualization of the subtle perfusion colors, causing them to appear darker or lighter than they should be. The inventors have solved this problem by allowing the opacities of both the tissue and the perfusion parameter colors to be varied. If the clinician want to appreciate the true coloration of the perfusion parameters unaffected by the display of tissue structure, the opacity of the tissue can be reduced or made transparent so the clinician can view the perfusion alone, unaffected by the tissue display. If the clinician want to orient the perfusion to tissue landmarks, the tissue opacity can be turned up to show the perfusion in relation to the tissue. Thus, the perfusion alone can be analyzed precisely in detail, or it can be shown in its tissue structure to orient the perfusion in the body. While conventional wisdom would say that the standard overlay of perfusion and tissue without variation should provide all that is needed, the present inventors have eschewed this conventional wisdom and enabled the opacities to be varied, even though neither image is obscuring the other. As a result subtle differences in perfusion in the same tissue can be appreciated and diagnosed. Pedrizzetti et al., in contrast, only enables comparison of perfusion properties between different patients or between different tissues, not the same tissue. See paragraph [0087] of Pedrizzetti et al. For these reasons it is respectfully submitted that the invention of Claims 2-4, 11 and 12 are patentable over Schwartz and Pedrizzetti et al.

It is also seen that Pedrizzetti et al. makes no mention of harmonic contrast agents. Schwartz makes no mention of any type of contrast agents. The echo signals returned from contrast agents are much weaker than those returned from neighboring tissue, which often makes the contrast signals difficult to detect. The invention of Claims 1 and 10 solves this problem by the use of harmonic contrast agents. Signals from tissue are received at fundamental frequencies. Signals from the harmonic contrast agent are received in a harmonic band, which permits their separation and detection on a frequency basis by filtering or pulse inversion as explained in the paragraph spanning pages 5-6 of the specification and in the paragraph beginning on page 12, line 13. It is respectfully submitted that Claims 1

and 10 and their dependent Claims 3-4 and 11 are patentable over Schwartz and Pedrizzetti et al. for this further reason.

Claims 5-9 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schwartz. As previously mentioned, Schwartz uses opacity control to enable a user to "see through" the tissue between the viewer and blood vessels which otherwise obscures the deeper blood vessels in a 3D image. The invention of Claims 5-9 and 13 is applicable to both 2D and 3D imaging and it is seen that the actual ultrasound images in the drawings of Figs. 15A-15E are in fact 2D planar images. In a 2D image of a single plane there is no structure in front to obscure deeper image structure as there is in a 3D image and hence one skilled in the art would take the approach of colorflow imaging and Pedrizzetti et al. which does not need any opacity variation. The problem of nearer tissue obscuring deeper vessels is simply not present. Accordingly it is respectfully submitted that Claims 1 and 10 and their dependent Claims 5-9 and 13 are patentable over Schwartz because one skilled in the art would see that the problem of Schwarz is not present in 2D imaging of tissue perfusion.

It is further noted that Claims 5-9 and 13 contain the limitations of Claims 1 and 10 from which they depend which describe other features not found in Schwartz, such as the use of harmonic contrast agents and parametric perfusion imaging rather than large vessel flow imaging. It is respectfully submitted that Claims 5-9 and 13 are patentable over Schwartz for these further reasons.

In view of the foregoing amendment and remarks, it is respectfully submitted that amended Claims 10-11 and 13-19 comply with the written description requirement, That Claims 1, 3 and 5-9 are directed to patentable subject matter, that Claims 1, 10 and 14-19 are not anticipated by Schwartz, and that Claims 3-9, 11 and 13 are patentable over Schwartz and Pedrizzetti et al. Accordingly it is respectfully requested that the rejection of Claims 10-11 and 13-19 under 35 U.S.C. §112(1), of Claims 1, 3, and 5-9 under 35 U.S.C. §101, of Claims 1, 10 and 14-19 under 35 U.S.C. §102(b) and of Claims 3-9, 11 and 13 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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